Exhibit 2

Defending the Republic

A Republic... if you can keep it. - Ben Franklin

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February 9, 2022

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
Via E-Mail: FDAFOIA@fda.hhs.gov

Re: FDA Freedom of Information Act Appeal; FOIA Control # 2022-908

To whom it may concern:

I write in response to FOIA Control # 2022-908. Our FOIA request to the Food and Drug Administration (FDA) asked the following: "Please provide all data and information submitted by Moderna relating to the FDA review and approval of Spikevax. This includes, but is not limited to, all safety and effectiveness data and information; all data and information in the biological product file; and all ingredients."

We made an expedited request pursuant to 5 U.S.C. § 552(a)(6)(E), which requires an agency to grant an expedited processing request where there is a "compelling need" for publication or as otherwise determined by the agency. Specifically, we requested expedited processing "under 5 U.S.C. § 552(a)(6)(E)(v)(II), as the requester has shown a compelling need for the processing of these records: it is urgent to inform the public of the Federal Government activity informed by the requested information."

In a February 9, 2022 letter, it was determined that our request does not meet the criteria for expedited processing under FOIA. It was stated that we have not "demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity."

Please consider this letter to be our appeal of this determination. It is without question that the public and the medical community have an urgent and compelling interest in analyzing the data and information underlying the FDA's approval of Moderna's COVID-19 vaccine. There is no debate that COVID-19 has touched every single American life. The Centers for Disease Control and Prevention (CDC) estimate that there have been over 146 million COVID-19 infections in this country, resulting in 7.5 million hospitalizations and causing 921,000 deaths.[1]

[1] CDC, Estimated COVID-19 Burden, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html.

The FDA recognizes the ongoing COVID-19 emergency, allowing for the continuation of Emergency Use Authorizations for COVID-19 vaccines. The basis for this determination was that there "is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19."[2]

Adding to the urgency are the federal, state, and local government mandates of COVID-19 vaccines. Hundreds of millions of Americans are, or could be, subject to these mandates. Approximately 10 million healthcare workers in an estimated 76,000 facilities are required to receive a COVID-19 vaccine.[3] Many of these providers are hesitant to receive the required vaccines, leading to fears, "particularly among nursing homes and smaller rural hospitals, that the mandate will exacerbate the existing staffing shortages that have crippled much of the country during this latest surge."[4] And in New York City, with a population exceeding 8 million people, citizens must show proof of vaccination to go to a restaurant, watch a ballgame, or go to the gym.[5]

The FDA promises "Spikevax meets the FDA's rigorous standards for safety, effectiveness and manufacturing quality required for approval."[6] The American people deserve to know whether that statement is true, especially since there are legitimate issues with Spikevax. And Americans deserve to have that information now, not years down the road. "Congress has long recognized that 'information is often useful only if it is timely.'" *Open Soc'y Just. Initiative v. Cent. Intel. Agency*, 399 F. Supp. 3d 161, 164 (S.D.N.Y. 2019) citing H.R. Rep. No. 93-876, at 6271 (1974). "[S]tale information is of little value." *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988).

For example, the FDA concedes there is "evidence from published observational studies of waning protection following primary vaccination and evidence of decreased effectiveness against some SARS-CoV-2 variants such as Omicron."[7] The waning effectiveness is evidenced by the FDA's concession that boosters "improve upon the benefits provided by the primary series" of Spikevax.[8] The FDA acknowledges "post-authorization safety surveillance has identified serious risks of myocarditis and pericarditis, particularly within 7 days following the second dose of Moderna

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[2] FDA, Review Memorandum of Moderna COVID-19 Vaccine at p. 6, Jan. 6, 2022, https://www.fda.gov/media/155548/download.
[3] Audra D.S. Burch and Reed Abelson, The New York Times, Hospitals Confront the Fallout From Supreme Court Ruling on Vaccine Mandate, Jan. 15, 2022, https://www.nytimes.com/2022/01/15/us/healthcare-workers-vaccine-mandate.html.
[4] *Id*.
[5] Dana Rubinstein, The New York Times, New York City Tries New Approach: Vaccine Mandate for Private Employers, Dec. 27, 2021, www.nytimes.com/2021/12/27/nyregion/nyc-vaccine-mandate.html.
[6] FDA, Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine, Jan. 31, 2022, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.
[7] FDA, Summary Basis for Regulatory Action for Spikevax at p. 28, Jan. 30, 2022, https://www.fda.gov/media/155931/download,
[8] *Id*. at p. 29.

COVID-19 Vaccine."[9] And the package insert for Spikevax says "[a]vailable data on SPIKEVAX administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy."[10]

A federal district court in the Northern District of Texas agrees with our assessment. On January 6, 2022, it ordered the expedited production of records relating to the FDA's approval of the Pfizer vaccine, concluding that it was "of paramount public importance." *Pub. Health & Med. Pros. for Transparency v. Food & Drug Admin.*, No. 4:21-CV-1058-P, 2022 WL 90237, at *1, 2 (N.D. Tex. Jan. 6, 2022). It stated "there may not be a "more important issue at the Food and Drug Administration ... than the pandemic, the Pfizer vaccine, getting every American vaccinated, and making sure that the American public is assured that this was not rushed on behalf of the United States." *Id*. (citations omitted) (cleaned up). The FDA was ordered to produce more than 12,000 by January 31, 2022; and 55,000 pages every 30 days thereafter, starting by March 1, 2022, until production was complete. *Id*.

For these reasons, we respectfully request the FDA reverse its decision, accept our request for expedited processing, and begin providing the requested data and information accordingly.

Very truly yours,

Travis W. Miller

Travis W. Miller

[9] *Id*. at p. 26.
[10] FDA, Spikevax Package Insert at p. 10, https://www.fda.gov/media/155675/download.